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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,296	09/13/2000	Patricia Anne Nuttall	2369-1-002	3816

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EXAMINER

BUNNER, BRIDGET E

ART UNIT PAPER NUMBER

1647

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/555,296

Applicant(s)

NUTTALL ET AL.

Examiner

Bridget E. Bunner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4, 6, 10, 18, 21-24, 29-32, 34 and 54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 54 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 6, 10, 18, 21-24, 29-32, 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 28 September 2006 has been entered in full. Claims 1, 4, and 34 are amended. Claim 54 is added. Claims 2-3, 5, 7-9, 11-17, 19-20, 25-28, 33, and 35-53 are cancelled.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4, 6, 10, 18, 21-24, 29-32, 34, and 54 are under consideration in the instant application.

### ***Withdrawn Objections and/or Rejections***

1. The objection to claim 1 as set forth at pg 2 of the previous Office Action (26 April 2006) is *withdrawn* in view of amended claim 1 (28 September 2006).
2. The rejections of claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34 under 35 U.S.C. § 112, first paragraph (enablement and written description) as set forth at pg 2-16 of the previous Office Action (26 April 2006) are *withdrawn* in view of Applicant's persuasive arguments and amendments to the claims (28 September 2006).

### ***New Claim Rejections - 35 USC § 112, first paragraph***

3. Claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 recites an isolated histamine or serotonin binding protein capable of binding to histamine or serotonin with a dissociation constant of less than  $10^{-7}$ M, wherein said isolated histamine or serotonin binding protein comprises (i) the amino acid sequence of SEQ ID NO: 4 or an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4 and (ii) has specific binding sites in SEQ ID NO: 4 or binding sites which are positioned in a functionally equivalent complementarity of shape in an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4. The claims also recite that a histamine or serotonin binding compound additionally comprises at residue V, a tyrosine residue, wherein residue V is positioned at residue 131 in SEQ ID NO: 4. The claims recite that the compound is stabilized by either or both disulphide bridges formed between cysteines 179 and 151 of SEQ ID NO: 4. Claim 10 recites that the histamine or serotonin binding compound comprises a synthetic protein. The claims also recite that the protein is produced by recombinant DNA technology, is derived from blood-feeding ectoparasites, spiders, scorpions, or snakes and venomous animals, and is bound to a resin support.

The specification as originally filed does not provide adequate written description for an isolated histamine or serotonin binding protein comprising an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4. The specification as originally filed also does not provide adequate written description for an isolated histamine or serotonin binding protein comprising an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4 and which has binding sites which are positioned in a

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functionally equivalent complementarity of shape in an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4. These limitations are not expressly asserted, nor do they flow naturally from the specification.

It is noted that at the top of pg 5 of the Response of 28 September 2006, Applicant states that support for the amendment to claim 1 is found in original claim 1; in the specification, for example, at pg 7, lines 9-12 and pg 16, lines 22-24; and Figure 4 and SEQ ID NO: 4 of the Sequence Listing. However, after examination of the entire specification, including the sections identified by Applicant, the Examiner was unable to find support for an isolated protein comprising an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4 and which has binding sites which are positioned in a functionally equivalent complementarity of shape in an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4.

### *Interview Summary*

On 20 November 2006, the Examiner discussed a proposed Examiner's amendment with Applicant's representative, Sarah Fashena via telephone. The Examiner proposed amending claim 1, lines 4-5 and 9-11 to remove recitation of an amino acid sequence having at least 90% homology to the amino acid sequence of SEQ ID NO: 4. The Examiner indicated that claims directed to an isolated protein comprising the amino acid sequence of SEQ ID NO: 4 and a method of treating allergic asthma by administering the protein would be allowable. Ms. Fashena declined the proposed Examiner's amendment.

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***Conclusion***

Claims 1, 4, 6, 10, 18, 21-24, 29-32, and 34 are rejected.

Claim 54 is allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BEB  
Art Unit 1647  
20 November 2006

*Bridget E. Bunner*

**BRIDGET BUNNER  
PATENT EXAMINER**